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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,371	05/16/2001	Alison Davies	DAV 13002REF	9780

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11/08/2005

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Alexandria, VA 22314-1176

EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 11/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/831,371

Applicant(s)

DAVIES, ALISON

Examiner

G. R. Ewoldt, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,4-9,11,14-16 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 2,4-9,11,14-16 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's amendment and remarks filed 8/22/05 are acknowledged.
2. Claims 2, 4-9, 11, 14-16, and 21 are pending and being acted upon.
3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
A person shall be entitled to a patent unless --
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
4. Claims 2, 4-9, 14, 16 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by the IDANT LABORATORIES Personal Blood Storage Brochure, as evidenced by the Feldschuh letter.

As set forth previously, The IDANT LABORATORIES Personal Blood Storage Brochure teaches a method of autologous transplantation of healthy mature blood (which would include T lymphocytes) obtained from a mature non-diseased human's blood, said cells having been harvested before the suggestion or suspicion of a disease (see entire brochure). Note particularly the transfusion for emergency surgery such as bone fractures (a condition for which the host would have no direct prediction, suggestion, or suspicion). The Feldschuh letter merely certifies that the brochure was printed in approximately 1994.

Applicant's arguments, filed 8/22/05, have been fully considered but they are not persuasive. Applicant argues that the reference "makes no mention of whether whole blood or whether one or more components of blood are stored. Thus, from this document alone, it cannot be ascertained whether or not the blood that was stored by Idant Laboratories included T lymphocytes". Applicant cites the Feldschuh letter. Applicant further cites *Safe Blood* (1990).

It is the Examiner's position that the reference says what it says, i.e., the storage of "blood". "Blood" has been defined as "the circulating tissue of the body ... including lymphocytes [which would include T cells]", see *Stedman's Medical Dictionary*, 24th Ed. (1998). Accordingly, the reference teaches the method of the claims. Neither *Safe Blood* nor the Feldschuh letter can change the teaching of the reference.

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Applicant argues that in "EP-A-0668013 (page 2), it is stated that white blood cells are routinely removed from blood preparations prior to storage, i.e.

"... blood drawn from the donors is centrifuged and separated in order to remove plasma and the buffer coat [which contains the white blood cells - see page 30, lines 36-37, of the current application] thereby producing concentrated red blood cells possessing a hematocrit value of 55-90%" (page 2, lines 29-31).

The above statement is exemplified by the Examples of EP-A-0668013 which refer almost exclusively to concentrated red blood cell fractions from which the white blood cells have been removed.

Applicant is advised that out of context quotes are not generally convincing. First, EP-A-0668013 is entitled "Freeze-dried blood cells, stem cells, and platelets and manufacturing method for same". The document is not concerned with the storage of blood, but rather particular blood components. More importantly, regarding Applicant's incomplete quote set forth above, the entire quote would actually disclose, "An example in which concentrated red blood cells (hematocrit value = 55 ~ 90%) are frozen will be explained hereinafter ...". It is not surprising that an example describing the concentration of red blood cells would include a method for their concentration.

Applicant argues that the claimed method now recites "an isolated host cell population of mature healthy lymphocytes obtained from blood".

The blood of the reference meets the limitation of the claims, i.e., the blood is isolated and it comprises lymphocytes.

5. Claims 2, 4-9, 14, 16, and 21 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by Feldschuh (1990).

As set forth previously, Feldschuh teaches a method of autologous transplantation of healthy mature blood (which would include T lymphocytes) obtained from a mature non-diseased human's blood, said cells having been harvested before the suggestion or suspicion of a disease (see Chapter 8, particularly Frozen Autologous Blood). The reference further teaches the freezing of blood to -318°F.

Applicant's arguments, filed 8/22/05, have been fully considered but they are not persuasive. Applicant argues that

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the reference does not teach the "isolated" T lymphocytes of the claims.

As set forth above, the reference meets the limitations of the claims, i.e., the blood is isolated and it comprises lymphocytes.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claim 11 stands rejected under 35 U.S.C. 103(a) as being unpatentable over the IDANT LABORATORIES Personal Blood Storage Brochure or Feldschuh in view of U.S. Patent No. 5,876,321 (of record).

As set forth previously, The IDANT LABORATORIES Personal Blood Storage Brochure and Feldschuh have been discussed above.

The reference teachings differ from the claimed invention only in that they do not teach a method further comprising using the lymphocytes in cancer therapy.

The '321 patent teaches the freezing of autologous white blood cells (which would comprise dormant lymphocytes) for later use in the treatment of cancer, and the advantages of the use of autologous cells, most specifically, safety (see particularly column 1, lines 48-64).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to perform a method of autologous transplantation of healthy mature lymphocytes (which would include T lymphocytes) obtained from a mature non-diseased human's blood, said cells having been harvested before the suggestion or suspicion of a disease, as taught by the IDANT LABORATORIES Personal Blood Storage Brochure or Feldschuh, wherein said cells had been frozen for later use in the treatment of cancer, as taught by the '321 patent. One of ordinary skill in the art at the time the invention was made would have been motivated to prepare and store said cells for the later treatment of cancer given the teachings of the '321 patent that it is safer to use autologous cells in cancer treatment.

Applicant's arguments, filed 8/22/05, have been fully considered but they are not persuasive. Applicant argues that "It should first be noted that the emphasis of both the Idant Brochure and Feldschuh (1990) is squarely on eliminating the possibility of infectious agents being transferred from a third-party blood donor to the recipient of the blood. As such, these

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documents do not address the issue which is the subject of the presently claimed invention, i.e. the use of autologous T lymphocytes for therapeutic purposes.

Applicant is advised that the references need merely teach the claimed limitations to comprise prior art.

Applicant argues, "Importantly, there is no suggestion whatsoever in the Idant Brochure, Feldschuh (1990) or the Feldschuh letter towards the storage of isolated host cell populations of mature, healthy lymphocytes for subsequent therapy. Consequently, there would have been no motivation on the person skilled in the art to combine the disclosures of any of these documents with other prior art documents.

Applicant is advised that the primary references teach the storage of isolated T lymphocytes (in the blood), and provide sufficient motivation for said storage, i.e., the safer use of autologous blood for future treatments.

Applicant cites WO 89/04168 as teaching away from the method of the combined references.

Applicant is advised that WO 89/04168 is not part of the instant rejection. Further, the intended uses and motivations of the combined references need not be the intended uses and motivations set forth elsewhere.

8. Claims 11 and 15 stand rejected under 35 U.S.C. 103(a) as being unpatentable over the IDANT LABORATORIES Personal Blood Storage Brochure or Feldschuh in view of Abe et al. (1996)

As set forth previously, The IDANT LABORATORIES Personal Blood Storage Brochure and Feldschuh have been discussed above.

The reference teachings differ from the claimed invention only in that they do not teach a method further comprising the use of genetically modified lymphocytes or the use of said cells in cancer therapy.

Abe et al. teaches the use of genetically modified lymphocytes in cancer therapy and that said cells have improved antitumor activity (see particularly page 165, Results).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to perform a method of autologous transplantation of healthy mature lymphocytes obtained from a mature non-diseased human's blood, said cells having been harvested before the suggestion or suspicion of a disease as taught by the IDANT LABORATORIES Personal Blood Storage Brochure or Feldschuh, wherein said cells had been genetically modified for use in cancer therapy, as taught by Abe et al.

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One of ordinary skill in the art at the time the invention was made would have been motivated to prepare, genetically modify, and store said cells for the later treatment of cancer, given the teachings of Abe et al. that said cells have improved antitumor activity.

Applicant's arguments, filed 8/22/05, have been fully considered but they are not persuasive. Applicant argues that the Abe et al. reference relates to a different field of technology and would not have been considered relevant to the skilled artisan.

It is the Examiner's position that the artisan skilled in the cellular therapy of cancer would be aware of genetically modified cells and, thus, the work of Abe et al.

9. No claim is allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

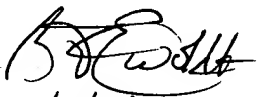
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

12. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications

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is available through Private PAIR only. For more information about the PAIR system, see www.pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Inquiries of a general nature may also be directed to the Technology Center 1600 Receptionist at (571) 272-1600.


11/2/04

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